

## **REMARKS**

### **I. Status of the Claims**

Claims 2-6, 8-13, 23-26, and 102 were examined and rejected by the Office. In accordance with the Request for Continued Examination (RCE), claims 3, 4, 5, 6, and 9 have been amended. The amendments to the claims are supported by the specification and do not add new matter. Specifically, the amendments to claims 3, 4, 5, 6, and 9, reciting "viable" oocysts, are supported by the specification at paragraphs [0004], [0021], [0022], [0026], [0027], [0030], [0031], [0039], [0040], [0045], [0066], [0069], [0084], [0114], [0151], [0154], [0159], [0160], [0162], and [0185], as well as originally filed claims 76, 90, 91, and 98-101. The Applicants respectfully request the Examiner to consider the following remarks in light of the pending claims, 2-6, 8-13, 23-26, and 102.

### **II. Specification Objections**

The paragraph numbers recited in the amendments to the specification have been corrected to correspond to the paragraph numbers of the instant specification, instead of the numbers in the published patent application (*i.e.*, PGPub). Amendments to the specification have been made to correctly denote and define trademarks or trade names. The specification has also been amended to add degree symbols. Amendments to the specification were also made to correct spelling errors. In light of the above-cited amendments, the Applicants respectfully request withdrawal of all objections to the specification.

### **III. Summary of the Claimed Invention**

As amended, the currently claimed invention recites methods for isolating a **viable oocyst** using a **hydrocyclone**. Nowhere in the prior art has it been disclosed, taught, or suggested that a hydrocyclone could be used to separate a viable oocyst. In fact, the prior art teaches away from using a hydrocyclone for use with living organisms, as it was previously expected to fatally damage the oocysts due to the intense sheer forces.

"[0084] In yet another embodiment, a hydrocyclone is used to concentrate the filtrate obtained from sieving. It has been discovered that a hydrocyclone, traditionally used in the petrochemical and environmental science fields is useful for concentrating oocysts. Hydrocyclones use the principle of centrifugal separation to remove or classify solid particles from a fluid, based on size, shape, and density. The use of a hydrocyclone, not known to be used for living organisms, was previously believed to fatally damage the oocysts due to intense sheer forces. The instant invention provides a method of utilizing a hydrocyclone to concentrate oocysts." Paragraph [0084], Originally Filed Patent Specification. (Emphasis Added).

In view of the above, it is respectfully submitted that the prior art does not disclose, teach, or suggest the currently claimed invention, which recites methods for separating a viable oocyst using a hydrocyclone.

#### IV. 35 U.S.C. § 103 Rejections

***(a) Pending claims 2-6, 8-10, and 23-26 are not rendered obvious by Conkle et al. in view of Singh et al.***

Reconsideration is requested of the rejection of claims 2-6, 8-10, and 23-26 under 35 U.S.C. §103(a) in view of Conkle *et al.* and Singh *et al.*<sup>1</sup>

Three criteria must be present to establish a *prima facie* case of obviousness.<sup>2</sup> First, the prior art reference must teach or suggest all the claim limitations. Second, there must be some reason for one of ordinary skill in the art to modify or combine the reference(s). Third, there must be a reasonable expectation of success.<sup>3</sup> Not one of these three criteria is satisfied by Conkle *et al.* and/or Singh *et al.*, either alone or in combination.

Currently amended claims 2-6, 8-10, and 23-26 require use of a hydrocyclone to separate viable oocysts from a liquid suspension.

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<sup>1</sup> Conkle *et al.*, WO 2000/50072; Singh *et al.* (1995) Cereal Chemistry 72(4):344-348.

<sup>2</sup> MPEP §2143.

<sup>3</sup> *Id.*

1. Neither Conkle *et al.* nor Singh *et al.*, either alone or in combination, disclose, teach, or suggest using a hydrocyclone to separate viable oocysts. Conkle *et al.* disclose a method for separating and isolating oocysts from *Eimeria* (*i.e.*, encysted protozoa) that uses a centrifuge to separate the oocysts from liquid suspensions. Nowhere do Conkle *et al.* disclose or suggest that a hydrocyclone could be used in their separation and isolation method. The Office Action specifically acknowledges that “Conkle *et al.* do not teach hydrocyclones.” See Office Action, page 5, line 14.

Singh *et al.* use a hydrocyclone to separate starch particles from protein particles in a solution of wet-milled corn. Nowhere do Singh *et al.* disclose or suggest that a hydrocyclone could be successfully used to separate and/or isolate viable oocysts from liquid suspensions. Moreover, Singh *et al.* does not cure the failings of Conkle *et al.*, as Singh *et al.* fails to provide hydrocyclones with viable oocysts or intact living organisms. The fact that the wet milling methods of Singh *et al.* inherently destroy cells to isolate starch and protein fragments further teach away from the element of separating a viable oocyst. Thus, Applicants respectfully assert that all claim limitations have not been taught or suggested, and that there is no *prima facie* case of obviousness.

2. At the time of filing, there was no reason or motivation for combining Conkle *et al.* and Singh *et al.* Specifically, one of skill in the art would have known that use of a hydrocyclone involves extreme sheer forces and that an oocyst may be fatally damaged from agitation, stirring, or shaking. See Originally Filed Patent Specification, paragraph [0084]. Therefore, the state of the art at the time of filing taught away from using a hydrocyclone to separate viable oocysts.

The Office Action asserts that it would have been obvious to use a hydrocyclone because Singh *et al.* taught that using a hydrocyclone “increased the yield of product, reduced the time required for separation, and eliminated the requirement of a large floor area.”<sup>4</sup> This reasoning, however, is not correct. The yield of cell fragments (*i.e.*, starch and protein) is not pertinent to the separation of viable oocysts. Singh *et al.*

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<sup>4</sup> Office Action mailed September 30, 2008, page 5, lines 15-25.

provides no disclosures, teachings, or suggestions for separating a viable oocyst or any other living organism.

Singh *et al.* compared the use of a hydrocyclone to separate **fractionated starch** from wet-milled corn with the traditional starch tabling procedure (*i.e.*, the use of long (~20 feet) sloped tables that allow starch granules to settle by gravity such that they can be separated from the liquid phase). While the advantages cited by Singh *et al.* may be significant for starch, they are not relevant to the methods used to separate **viable oocysts** from a liquid suspension, as required by the method of claims 2-6, 8-10, and 23-26.

"A *prima facie* case of obviousness may be rebutted by showing that the prior art, in any material way, teaches away from the claimed invention." *In re Geisler*, 116 F.3d 1465, 1471; 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). "When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious." *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395 (2007). Applicants respectfully assert that there was no motivation to modify or combine the references as proposed by the Office Action, and that there is no *prima facie* case of obviousness.

3. Even if the Conkle *et al.* and Singh *et al.* reference had been combined as proposed by the Office Action, Applicants assert there would have no reasonable expectation of success as required by § 103. As noted above, the reliance on Singh *et al.* is mistaken since the isolation of starch in wet milling would have been known in the art to necessarily include grinding the cell walls into small fibers or fragments. In support of this fact, Applicants refer the Examiner to the following passage that is generally reflective of the starch milling.

"Whereas in the potato starch manufacture grating normally takes place at least twice, wherein the fibre size in the first grated substance is in the order of 0.4 mm, in the method described in Dutch Pat. No. 77,039 it was considered necessary to grate the potatoes in one time **to a particle size of less than 0.17 mm to obtain a good starch production and also to avoid clogging of the cyclones.** A disadvantage of this method is that **the cell walls of the potatoes are ground to such small fibres**

**that the resulting fine fiber is separated less easily from the starch granules in the hydrocyclone separator** than with the usual grinding degree and that it is also difficult to sieve them from the overflow of the hydrocyclone plant consisting of juice and fine fiber." See, e.g., U.S. Patent No. 3,890,888, col. 1, lines 27-40.

In view of the above, the Office Action's proposed combination of Singh *et al.* and Conkle *et al.* would have resulted in grinding the cell walls of the oocysts to avoid clogging the hydrocyclones, and would not be expected to yield a viable oocyst, as currently claimed.

Because the disclosure of Conkle *et al.* and Singh *et al.*, when taken singly or combined, do not teach or suggest all of the presently pending claim limitations, do not provide some suggestion or motivation to modify the reference teaching, and do not provide a reasonable expectation of success if the references were combined, a *prima facie* case of obviousness **has not been established**.

4. **Singh et al. is non-analogous prior art** that has been mistakenly cited by the Office. In order to rely on a reference in an obvious rejection, it must be analogous prior art. Analogous prior art must be either in the field of the Applicants' endeavor or it must be reasonably pertinent to the particular problem with which the Applicants were concerned. Neither rationale applies to the Singh *et al.* reference. Singh *et al.* is directed to wet milling (grinding, cutting, etc.), which is not the same technological field as separation of viable organisms. Moreover, the specific problem of shattering corn into cell fragments is not pertinent to the problem of isolating a viable oocyst from aqueous cell suspensions.

Because the methods described in Singh *et al.* would result in shattered cell fragments (protein and starch) and a non-viable cell, Singh *et al.* is plainly non-analogous art. Accordingly, **Singh et al. reference is not in field of Applicants' endeavor nor reasonably pertinent to the particular problem the present Applicants' solved**. A skilled artisan would not be motivated to look to the teachings of Singh *et al.* to provide guidance because Singh *et al.* presupposes the cell is ruptured into small fragments and is non-viable. In view of the foregoing, Singh *et al.* cannot be properly used by the Office in an obviousness rejection against the present invention.

5. The Applicants further re-assert that U.S. Patent No. 5,547,858 ("the '858 patent), directed to a "Method for purification of amino acids, nucleic acids using a hydrocyclone" fails to disclose, teach, or suggest the separation of any viable oocyst using a hydrocyclone. (Emphasis Added). Among other factors, one of skill in the art would understand that the '858 patent teaches away from the currently claimed invention as the amino acids and nucleic acids being isolated by the '858 patent are taken from cells which are no longer intact or viable. In no instance does the '858 patent describe the separation of any viable oocyst from aqueous cell suspensions. It is respectfully submitted that the U.S. Patent No. 5,547,858 only discusses isolation of crystals having a diameter larger than cells, and does not identify isolation of a viable oocyst. Perhaps most importantly, the '858 patent states that separation of cells from similarly sized particles is impossible.

"[W]hen a solution containing cells is fed to the liquid cyclone, the cells have a diameter, smaller than the critical diameter so that there is no difference in concentration between the upstream and the downstream of the liquid cyclone, which makes separation of the cells impossible."  
U.S. Patent No. 5,547,858, col. 1, lines 31 to 49. (Emphasis Added).

As noted previously, the prior art teaches away from use of a hydrocyclone to separate living cells from aqueous cell suspensions. The prevailing view at the time the invention was filed, in fact, was that it was not possible to separate living cells from aqueous cell suspensions using a hydrocyclone.

6. As an additional or alternative basis for allowance of the pending claims, Applicants further assert that using a hydrocyclone to separate viable oocysts was an unexpected result that rebuts any *prima facie* case of obviousness. The above indications of non-obviousness are further consistent with the Conkle *et al.* reference, which indicates that shaking, stirring, and combinations thereof may destroy oocysts.

"Overall, the agitation level should be sufficient to fully suspend all solids during sporulation but not enough to destroy the oocysts. This may occur through aeration,

**shaking, stirring, and combinations thereof.** Conkle *et al.* page 7, lines 31-33. (Emphasis Added).

The currently claimed invention is therefore surprising and unexpected in view of Conkle *et al.* These unexpected results are commensurate with the scope of the claims, which specifically recite use of a hydrocyclone to separate a viable oocyst.

7. Applicants respectfully assert that the Office Action's reliance on *KSR International CO. V. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), is misplaced. The proposed combination of Conkle *et al.* and Singh *et al.* under §103 does not involve using "similar methods in the same way" or any "predictable results." Rather, Conkle *et al.* expressly states that agitation may "destroy the oocysts" and Singh *et al.* inherently relies on wet milling to fractionate corn cells into starch and protein fragments (*i.e.*, not viable oocysts or living organisms). The currently claimed invention describes an unexpected result in using hydrocyclones to separate viable oocysts. Accordingly, the Applicants respectfully submit that *KSR* does not properly apply.

8. Applicants thank the Examiner for the comments regarding hindsight bias. The Examiner is correct that reference can only be made to "knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure." See Office Action, page 10, lines 1-4. Applicants respectfully submit that the currently amended claims are in condition for allowance, as the recited elements were **not within the level of ordinary skill at the time the claimed invention was made.** In fact, it has been shown that it was unexpected that a hydrocyclone could be used to separate a viable oocyst.

In view of the foregoing, the Applicants respectfully request withdrawal of the obviousness rejections of pending claims 2-6, 8-10, and 23-26 under Conkle *et al.* in view of Singh *et al.*

***(b) Rejection of claims 11-13 under U.S.C. § 103(a)***

Reconsideration is requested of the rejection of claims 11-13 under 35 U.S.C. §103 (a) in view of Conkle *et al.*, Singh *et al.*, and in further view of Sjoerdsma *et al.*<sup>5</sup>

Claims 11-13 each require use of a hydrocyclone to separate viable oocysts. For all of the reasons detailed in section IV(a), use of a hydrocyclone to separate viable oocysts as required by claims 11-13 is not obvious in view of the cited art. The above arguments from section IV(a) are hereby incorporated and reasserted.

The defect in the Office Action's obviousness rejection is not cured by resort to Sjoerdsma *et al.*, either alone or in combination with Conkle *et al.* and Singh *et al.* The Office Action states that, "Sjoerdsma *et al.* teach that mesh screens can be used to extract debris from biological material (Example 6, column 24)." Reliance on Sjoerdsma, however, is misplaced as the cited reference does not refer to the separation of any viable oocysts or any living organism, but only a mixture of 2-difluoromethyl-2,5-diaminopentanoic acid, corn starch, lactose, and zinc stearate. Importantly, Sjoerdsma *et al.* does not disclose, teach, or suggest use of a hydrocyclone to separate viable oocysts. The reference only discloses that mesh screens can be used to extract debris from a starch paste (See Sjoerdsma *et al.*, Example 6, column 24, lines 28-34).

In view of the foregoing, the Applicants respectfully request withdrawal of the obviousness rejections of pending claims 11-13 under Conkle *et al.* in view of Singh *et al.* in further view of Sjoerdsma *et al.*

**(c) Rejection of claim 102 under U.S.C. § 103(a)**

Reconsideration is requested of the rejection of claim 102 under 35 U.S.C. §103(a) in view of Conkle *et al.*, Singh *et al.*, as applied to claims 2-6, 8-10, and 23-26 above, and in further view of Kimura *et al.*<sup>6</sup>

Claim 102 requires use of a hydrocyclone to separate viable oocysts. For all of the reasons detailed in section IV(a), use of a hydrocyclone to separate viable oocysts

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<sup>5</sup> Conkle *et al.*, WO 2000/50072; Singh *et al.* (1995), *Cereal Chemistry* 72(4):344-348; Sjoerdsma *et al.*, U.S. Patent No. 4,399,151, published August 16, 1983.

<sup>6</sup> Conkle *et al.*, WO 2000/50072; Singh *et al.* (1995), *Cereal Chemistry* 72(4):344-348; Kimura *et al.*, *Journal of Protozoology Research*, July 2000, vol. 10, No. 3, pp. 155-165 (Abstract only).



as required by claim 102 is not obvious in view of the cited art. The above arguments from section IV(a) are hereby incorporated and reasserted.

The defect in the Office's obviousness rejection is not cured by resort to Kimura *et al.*, either alone or in combination with Conkle *et al.* and Singh *et al.* The Office Action states that "Kimura *et al.* teach a flotation technique using sucrose (see the Abstract). . ." See Office Action, page 13, lines 7-10. However, as with the other cited art, Kimura **fails to disclose, teach, or suggest any use of a hydrocyclone to separate viable oocyst**, as currently claimed. Even in the flotation technique of Kimura, **"the recovery rate from high turbidity water was significantly lower."** which may be considered a teaching away from the currently claimed invention. At the time of filing, there would have been no expectation of success in using a hydrocyclone to separate a viable oocyst, since such a method would have been expected to fatally damage the oocysts. As such, Kimura *et al.*, either alone or in combination with Conkle *et al.* and Singh *et al.* fail to disclose, teach, or suggest all elements that are recited in claim 102.

In view of the foregoing, the Applicants respectfully request withdrawal of the obviousness rejections of pending claim 102 under Conkle *et al.*, Singh *et al.*, and Kimura *et al.*, either alone or in combination.

## **V. Conclusions**

In light of the foregoing, the Applicants request entry of amendments to the specification and claims, withdrawal of the specification objections and claim rejections, and solicit an allowance of all pending claims, *i.e.*, claims 2-6, 8-10, 23-26, and 102.

The Commissioner is hereby authorized to change any and all fees that may be required or credit any overpayment to Deposit Account No. 50-1662.

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Respectfully Submitted,

**PATENT**

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